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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,985	02/26/2004	Chuang Chun Chiueh	CHIU3034/EM	2667

23364 7590 08/01/2005

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/785,985	CHIUEH, CHUANG CHUN	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-19 are pending and under examination. Please direct all further correspondence to Art Unit 1648, Examiner Stacy Chen.

Claim Objections

2. Claims 1-4, 16, 17 and 19 are objected to for the following minor informalities: Proper Markush group language is "selected from the group consisting of", not "selected from a group consisting of".

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to preventative (prophylactic) agents against any and all viral infections comprising compositions containing varying amounts of C-phycocyanin and/or allophycocyanin and/or spirulina growth factor. Applicant has not demonstrated the preventative effects of any or all of C-phycocyanin and/or allophycocyanin and/or spirulina growth factor. In order for prevention to be demonstrated, suitable animal models must be challenged with the appropriate pathogen after

having been previously treated with C-phycocyanin and/or allophycocyanin and/or spirulina growth factor. Applicant has not shown experiments or literature that supports the instant claims to prevention of all viral infections. One of skill in the art would not expect C-phycocyanin and/or allophycocyanin and/or spirulina growth factor to completely prevent viral infection of any virus without having seen proof that it works in at least an acceptable animal model of disease. Therefore, the claims as written are not enabled for their intended use as a preventative measure against viral infection.

Hirahashi *et al.* (*International Immunopharmacology*, 2002, 2 :423-434) discloses that *Spirulina*, which inherently contains C-phycocyanin, allophycocyanin and spirulina growth factor, has anti-viral effects in humans (abstract and page 423, second column, last sentence). However, no results of complete prevention of viral infection have been achieved. Suggested language to overcome this enablement rejection is "oral agent that treats viral infection".

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, 6-11 and 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- When referring to ranges in claim 3, for example, "1:1 ~ 1:10", the tilden renders the claim indefinite because one cannot determine if the range is about 1:1 to about 1:10, or if the range is 1:1 to about 1:10, or if the range is about 1:1 to 1:10, etc. If

Applicant intends to claim loose ranges, suggested language is "1:1 to about 1:10", for example. Otherwise, the metes and bounds of the claims cannot be determined.

- When notating formulas in claim 8, for example, "3 ~ 45% C-phycocyanin", it is unclear why both the "3" and "45%" are present in the claims. The tildens confuse the claims language so that one of skill cannot interpret their meaning.
- The term, "phycocyanin" in claim 15 has no antecedent basis in claim 14. If Applicant intends to include both c-phycocyanin and allophycocyanin in the term "phycocyanin", then the claims must clearly reflect that the first time the term, "phycocyanin" is used in the claims. Correction is required to overcome this rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirahashi *et al.* (*International Immunopharmacology*, 2002, 2 :423-434, "Hirahashi"). Note that the claims are rejected only for their enabled embodiments. In this case, the oral agent is not prophylactic, rather a treatment agent. The claims are drawn to an oral agent against viral infection comprising C-phycocyanin and/or allophycocyanin and/or spirulina growth factor. The C-

phycocyanin and/or allophycocyanin and/or spirulina growth factor is in a water-soluble formula, such as a powder or granule.

Hirahashi discloses that *Spirulina*, which naturally contains C-phycocyanin, allophycocyanin and spirulina growth factor, has anti-viral effects in humans (absract and page 423, second column, last sentence). In a study that Hirahashi conducted, 12 healthy male volunteers were administered 50 mL of Spirulina extract orally every day. The soluble extract was prepared from a spray-dried powder of *S. platensis* (page 424, second column). The instant claim limitations are met by the teachings of Hirahashi and are therefore anticipated.

6. Claims 1, 2, 17 and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Gemma *et al.* (*The Journal of Neuroscience*, July 2002, 22(14):6114-5120, "Gemma"). Note that the claims are rejected only for their enabled embodiments. In this case, the oral agent is not prophylactic, rather a treatment agent. The claims are drawn to an oral agent against viral infection comprising C-phycocyanin and/or allophycocyanin and/or spirulina growth factor. The C-phycocyanin and/or allophycocyanin and/or spirulina growth factor is in an enteric-coated formula.

Gemma discloses the administration of spirulina supplement (0.33% w/w dry spirulina) to rats by blending the regular diet and spirulina into a dry powder and then administering by oral gavage with 0.5 mL of water, or in rat chow (page 6115, first column, "Materials and Methods" section). By nature, spirulina contains C-phycocyanin, allophycocyanin and spirulina growth factor. While Gemma does not disclose the treatment of viral infection, however, treatment is an intended use that does not carry patentable weight in the claims. Gemma's

product is expected to have the same functions and properties as Applicant's product. The limitations of the claims are met by Gemma's composition and are therefore anticipated.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirahashi and Gemma. The claims are drawn to an oral agent against viral infection comprising C-phycocyanin, allophycocyanin and spirulina growth factor. By nature, spirulina contains C-phycocyanin, allophycocyanin and spirulina growth factor. The compounds are in both water-soluble and enteric-coated formulas. Various concentrations and ratios of the compounds and additives/emulsifying agents are claimed. The teachings of Hirahashi and Gemma are summarized above.

Neither Hirahashi or Gemma teach a combination of water-soluble and enteric-coated forms of spirulina. Neither Hirahashi or Gemma teach the various concentrations of compounds instantly claimed.

Chapter 2144 of the MPEP discusses the subject of obviousness. The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent

established by prior case law. In the instant case, Applicant is combining two products that are the same in structure and function, with the exception that the compounds are in different formulations – water soluble and enteric-coated. MPEP 2144.06 discusses the combination of equivalents known for the same purpose. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious). But see In re Geiger, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987) ("Based upon the prior art and the fact that each of the three components of the composition used in the claimed method is conventionally employed in the art for treating cooling water systems, the board held that it would have been prima facie obvious, within the meaning of 35 U.S.C. 103, to employ these components in combination for their known functions and to optimize the amount of each additive.... Appellant argues... hindsight reconstruction or at best,... obvious to try'.... We agree with appellant."). The common function of spirulina taught by Hirahashi and Gemma is the ability to increase levels of cytokines (see

respective abstracts), not to mention the fact that both products are themselves spirulina. So the identity and the function of the spirulinas are the same. Therefore, one would have been motivated to combine the known products because the products are the same in content and function. Given that the products are the same in structure and function, one would have had a reasonable expectation of success that combining the two products would have worked

With regard to the various concentrations of the compounds claimed, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. It would have been obvious and well within the skill of the ordinary artisan to optimize the concentrations of spirulina and its components. Unless there is evidence indicating such concentrations discovered by Applicant are critical to the invention, they do not render the claims patentable over Hirahashi and Gemma. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

8. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Stacy B. Chen
July 29, 2005